UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01- 12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Hon. Patti B. Saris** **Magistrate Judge** **Marianne B. Bowler**

DEFENDANTS DEY, INC., DEY, L.P., AND DEY L.P., INC.'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS THE RELATOR'S COMPLAINTS FOR LACK OF SUBJECT MATTER JURISDICTION

PRELIMINARY STATEMENT

Ven-A-Care[1] cannot dispute that there have been public reports regarding "inflated" published prices, "marketing the spread," and purported over-reimbursements made by Medicare and Medicaid, including for the specific inhalation drugs at issue in this action since well since before Ven-A-Care claims to have learned of the alleged wrongdoing by Dey. *See* Ven-A-Care of the Florida Keys, Inc.'s Combined Opposition to Motions to Dismiss Filed by Abbott, Dey, and Roxane ("Opp. Brief"), at 16. The Government's investigation dating back to the 1960s "set the Government squarely on the trail of fraud such that it would not have been difficult for the Government to identify a potential wrongdoer." *In re Pharmaceutical Industry AWP Litigation (U.S. ex rel. West v. Ortho-McNeil Pharm., Inc.)* 538 F. Supp. 2d 367, 383, n. 10 (D. Mass. 2008). Ven-A-Care's arguments that some of these public disclosures do not sufficiently

[1] The capitalized and abbreviated terms used herein shall have the same definitions ascribed to them as in Dey's Memorandum of Law in Support of its Motion to Dismiss the Relator's Complaints for Lack of Subject Matter Jurisdiction, (Docket No. 6209) ("Opening Brief").

disclose fraudulent intent and that others are not specific enough to identify Dey miss the mark. Taken as a whole they demonstrate that all of the information upon which Ven-A-Care rests its claims was available to the general public before Ven-A-Care brought its claims against in August 1997 for Dey's albuterol sulfate and cromolyn sodium drugs, and in December 1999 for Dey's ipratropium bromide. In short, Ven-A-Care has failed to carry its burden of negating the bar. There have been public disclosures in the manner specified in the statute and Ven-A-Care's suit is based upon those disclosures. Accordingly, 31 U.S.C. § 3730(e)(4)(A) deprives this Court of subject matter jurisdiction over Ven-A-Care's claims. *See United States ex rel. Ondis v. City of Woonsocket*, No. 08-2389, __ F.3d __, Slip. Op. at 7-18 (1st Cir. Nov. 18, 2009)

Nor does Ven-A-Care fit within the "original source" exception to the public disclosure because it was the United States' investigatory efforts – not Ven-A-Care's – that first unearthed the information that forms the basis of the claims against Dey. Thus, Ven-A-Care has no direct or independent knowledge concerning Dey and therefore cannot avail itself of the "escape hatch" from the public disclosure bar. *See id.* at 18. Ven-A-Care has obscured this issue by filing a joint brief and grouping its "original source" arguments regarding Dey with arguments concerning Abbott and Roxane along with statements about its claimed knowledge about other unrelated instances of alleged Medicaid and Medicare fraud. What Ven-A-Care may or may not know about the conduct of other drug companies is simply not relevant as to whether it has "direct and independent knowledge" concerning Dey. Here, the evidence demonstrates that Ven-A-Care merely collected and summarized second-hand information relating to Dey at the request of the Government in connection with a Government-initiated investigation. This is not sufficient to fit Ven-A-Care within the "original source" exception.

Accordingly, the Court lacks subject matter jurisdiction over Ven-A-Care as a plaintiff-relator in this action. As this Court has already held, if subject matter jurisdiction over Ven-A-Care is lacking, the United States' complaint in intervention cannot relate back to Ven-A-Care's original *qui tam* complaints. *In re Pharm. Indus. Average Wholesale Price Litig. (U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc.)*, 498 F.Supp.2d 389, 399-400 (D. Mass. 2007). It is well-established that a subsequently filed complaint cannot relate back to a prior complaint over which the court lacked subject matter jurisdiction. The United States has not offered any authority to contradict this well-settled principal and instead cites only to one case and one statute that are silent on the subject. Therefore, the Court should grant summary judgment barring any recovery by the United States for claims that accrued more than six years before the United States filed its Complaint in Intervention on August 22, 2006.

I. THE CLAIMS AGAINST DEY ARE BASED ON PUBLICL DISCLOSURES

Ven-A-Care's tactic of arguing that each of the documents cited by Dey, on its own, cannot be a public disclosure in turn misstates applicable law. There is no requirement that the entire alleged scheme be disclosed in a single document; the "public disclosure" bar is triggered when the allegedly false set of facts and the true set of facts are publicly disclosed, whether together or in separate instances, as long as the disclosures lead to a plausible inference of fraud. *See Ondis*, __ F.3d __, Slip. Op. at 8. Ven-A-Care cannot dispute that the cumulative effect of these disclosures was to put the so-called scheme that Ven-A-Care alleges in its *qui tam* complaints squarely before the public.

A. The OIG Reports Concerning Albuterol and Ipratropium Alone Trigger the Public Disclosure Bar

The June 1996 Pharmacy Report, the June 1996 Suppliers Report, and the August 1998 VA Report are sufficient on their own to trigger the public disclosure bar because they contain

the essential elements of Ven-A-Care's claims against Dey and are among the expressly enumerated disclosure sources in section 3730(e)(4)(A). As the First Circuit recently held, the public disclosure bar applies when "the relator's allegations are substantially similar to allegations or transactions already in the public domain at the time he brings his *qui tam* action." *Ondis*, __ F.3d __, Slip. Op. at 17. Ven-A-Care does not (because it cannot) dispute that these reports contain all of the essential elements of its claims against Dey. Instead, Ven-A-Care contends that the reports are not sufficient to trigger the public disclosure bar because they do not include any mention of a fraudulent intent. This argument ignores the law. As this Court and other have repeatedly held:

> "[I]f X +Y=Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed." Under the framework, X stands for the allegedly false set of facts set forth in the claim at issue, and Y is a proxy for the allegedly true set of facts. Thus "when X [the false set of facts] *and* Y [the true set of facts] surface publicly, or when Z is broadcast… there is little need for qui tam actions" and the claim will be barred.

United States ex rel. O'Keeffe v. Sverdup Corp., 131 F. Supp. 2d 87, 94 (D. Mass. 2001) (quoting *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 655 (D.C. Cir. 1994) (citations omitted));*United States ex rel Ven-A-Care of the Florida Keys, Inc. v Actavis Mid-Atlantic LLC*, No. 08-CV-10852-PBS, 2009 U.S. Dist. LEXIS 92945 (D. Mass. Oct. 2, 2009) (same). In other words, when the allegedly false set of facts and the true set of facts forming the basis of a relator's FCA claim are publicly revealed, there is no need that an allegation of fraud need also be made publicly for the public disclosure bar to be triggered. Indeed, the "X" and the "Y" may come from different sources, so long as the disclosures together lead to a plausible inference of fraud. *Ondis*, __ F.3d __, Slip. Op. at 8.

In this case, the Pharmacy Report, Suppliers Report, and VA Report disclose both the X – the published prices – and the Y – the prices paid by providers. The spreads for Albuterol UD reported in the Suppliers Report and the Pharmacy Report, which were published more than a year before Ven-A-Care filed its first claims against Dey in Florida II Complaint in August 1997 – are almost identical to the spreads for Albuterol UD that appear in the Florida II Complaint. *Compare* SJ Ex. 48 at 5, SJ Ex. 49 at 6-7 *to* SJ Ex. 94 at Table 1, p. 47.[2] The spread for Ipratropium disclosed in the VA Report in August of 1998 is actually greater than the spread alleged by Ven-A-Care a year later in the Florida III Complaint, which contains the first reference to Dey's Ipratropium in this action. *Compare* SJ Ex. 51, at App. B. *to* SJ Ex. 95, at 141-42. Because both the "X" and the "Y" were already disclosed, the "Z" can be inferred. Ven-A-Care's characterization of the publicly disclosed information as "fraud" without any additional independent facts is not sufficient to avoid the bar.[3]

The Dey-specific sections in Ven-A-Care's *qui tam* complaints consist solely of charts setting forth spreads between the published prices and the prices at which Ven-A-Care claimed it could have bought Dey's drugs, and the allegation that Dey caused to be published "false" prices for its drugs. *See, e.g.* SJ Ex. 94, at ¶¶ 120-121. There are no allegations that Dey actively marketed the spread to induce providers to dispense its drugs instead of others or engaged in other conduct concerning the spread. Indeed, there is no evidence that Ven-A-Care ever purchased any of Dey's drugs before filing the Florida II Complaint. Accordingly, all of the

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2 The abbreviation "SJ Ex. __" refers to exhibits to the Declaration of Sarah L. Reid in Support of Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion for Partial Summary Judgment (Docket No. 6184).

3 Ven-A-Care relies heavily on this Court's opinion in *United states ex rel. Ven-A-Care of the Florida Keys, Inc. v. Actavis Mid-Atlantic LLC*, 2009 U.S. Dist. LEXIS 92945, to support its argument these reports are not public disclosures. In *Actavis*, the Court held that the public disclosure bar was not triggered because there was no disclosure of the "Y" or the "Z". Here, Dey has shown ample evidence of the "X", the "Y", and, as discussed *infra* at point II.B., the "Z".

allegations in Ven-A-Care's complaints regarding Dey were disclosed in the Reports and indeed mirror those reports. Thus, Ven-A-Care's allegations are "based upon" the public disclosures in the reports. *Ondis*, __ F.3d __, Slip. Op. at 17

Ven-A-Care's contention that there is no public disclosure because the Pharmacy, Suppliers, and VA Report do not reference Dey by name lacks legal support as well. As this Court has concluded, the public disclosure need not name the specific defendant at issue, provided the disclosure "'put the government squarely on the trail of the fraud' such that it would not have been difficult for the government to identify … a potential wrongdoer." *West v.* , 538 F. Supp. 2d at 383, n. 10 (quoting *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 571-72 (10th Cir. 1995)). Ven-A-Care does not dispute that Dey was one of only ten manufacturers of Albuterol UD at the time the Pharmacy and Suppliers Reports were published, and that it was one of only three manufacturers of Ipratropium at the time the VA Report was published, as reflected in the publicly available pricing compendia. *See* Exs. 30, 31.[4] Moreover, Ven-A-Care makes no attempt to distinguish from the defendants in *United States ex rel. Gear v. Emergency Medical Associates, Inc.*, 436 F.3d 726, 729 (7th Cir. 2006) – who submitted bills to Medicare on behalf of one of 125 teaching hospitals investigated by the OIG for improperly billing Medicare for services provided by hospital residents – or the defendants in *In re Natural Gas Royalties Qui Tam Litigation,* 562 F.3d 1032, 1038 (10th Cir. 2009) – who were among 200 natural gas drilling companies investigated by the GAO for not paying sufficient royalties for drilling on federal land. In both cases, reports prepared by the GAO and OIG were sufficient to

[4] The abbreviation "Ex. __" refers to exhibits to the Declaration of Sarah L. Reid in Support of Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion to Dismiss the Relator's Complaints for Lack of Subject Matter Jurisdiction (Docket No. 6208) and the Declaration of Sarah L. Reid in Further Support of Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion to Dismiss the Relator's Complaints for Lack of Subject Matter Jurisdiction (which is being filed concurrently with this brief.).

trigger the public disclosure bar, even though they did not name the specific defendants, or any other individual entities, and only discussed the practice at issue in a general fashion. *Gear*, 436 F.3d at 728; *Natural Gas*, 562 F.3d at 1042. Ven-A-Care offers no explanation for how the defendants in *Gear* and *Natural Gas* could be identifiable from the GAO and OIG reports in those cases – both of which were targeted at pools of over 100 possible defendants – but Dey could not be identifiable as one of only ten Albuterol UD manufacturers from the Pharmacy and Suppliers Reports, much less as one of only three Ipratropium manufacturers from the VA Report.

Ven-A-Care also contends that the VA Report is not a sufficient public disclosure as to Dey's Ipratropium because "[p]rices available to the VA are vastly different than prices available in the retail pharmaceutical market." Opp. Brief at 39. In fact, the opposite is true. The VA purchases drugs through the Federal Supply Schedule ("FSS") program, which negotiates prices with manufacturers based on the prices the manufacturers offer their best non-governmental customers. *See* SJ Exs. 43, at 8-10, 44, 45. While the prices available to the VA may be lower than the prices available to a small, independent pharmacy, they are certainly reflective of prices at which Dey's drugs are available in the marketplace. The so-called "average sales prices" as calculated by the United States' expert Simon Platt confirm this, as they are almost identical to the FSS prices for all of Dey's Subject Drugs, including Ipratropium, throughout the relevant time period. *See* SJ Ex. 406 at Figures A-C; *see generally id.* at Figures D-K.

B. Other Government Reports and News Media Articles Also Disclose The "X", the "Y" and the "Z" of Ven-A-Care's FCA Claims

In addition to the Pharmacy Report, the Suppliers Report, and the VA Report, all of the essential elements of Ven-A-Care's claims against Dey have been disclosed in government reports dating back to the late 1960s and news media articles dating back to the mid 1980s. As

set forth more fully in the Opening Brief, the public record is replete with disclosures regarding the "X" or the allegedly false state of affairs, namely that published prices do not reflect providers' actual costs (*see e.g.*, Ex. 24, at 3) the "Y" or the purportedly true state of affairs, namely what providers actually pay for the drugs at issue (*see, e.g.*, SJ Ex. 48, at 5) and the "Z" or allegations of the alleged fraudulent conduct (*see, e.g.*, Ex. 26 at 1). *See generally*, Opening Brief, at 7-9.

C. The "Spreads" Were Disclosed By the Publication of Dey's AWPs and WACs

Ven-A-Care does not dispute that comparing the published AWPs to the published WACs for Dey's drugs reveals so-called "mega-spreads" for those drugs. Instead, Ven-A-Care contends – without any legal support – that these AWPs and WACs were not publicly disclosed because they did not appear in the "news media or other publication set forth in the statute." (Opp. at 40.) Ven-A-Care's interpretation of "news media" as the term is used in section 3730(e)(4)(A) is far too narrow. Any information that is disseminated to the public in a periodic manner and is generally accessible to a stranger to the fraud qualifies as "news media" for the purposes of the statute. *See United States ex rel Alcohol Foundation, Inc. v. Kalmanovitz Charitable Foundation, Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002). In *Kalmanovitz*, the court held that scientific and technical journals that had limited audiences were "news media" under 3730(e)(4)(a) because "like newspaper reporters, scholarly and scientific authors also disseminate information to the public in a periodic manner" and "such sources are as generally accessible to any other strangers to the fraud as would be a newspaper article." *Id.* The same is true for Red Book, First DataBank, and the other pricing compendia in which Dey's AWPs and WACs appear. It is uncontested that they were used by the OIG in preparing its reports. Further, Ven-A-Care's own 30(b)(6) designee confirmed that they were "in the Library of Congress" and readily available to anyone who was willing to purchase them. *See* Ex. 47 at 895:5-12. These

publications are disseminated to the public and the Government in a periodic manner and are generally accessible to any person who would otherwise be a stranger to the transactions at issue in this action.

D. The OIG's Investigations Disclosed the Basis for the Claims Against Dey

Ven-A-Care does not even attempt to dispute that the OIG's investigations into the differences between AWPs and providers' actual costs for inhalation drugs were disclosed to it well before it first added Dey to its *qui tam* complaints. As set forth in Dey's opening brief, principals of Ven-A-Care confirmed that Ven-A-Care was aware of the OIG's investigations as early as 1994. *See* Ex. 37, at 417:21-418:18. Indeed, when the investigations were first commenced, Ven-A-Care's affiliate, the Cobo Pharmacy (which was operated by a principal of Ven-A-Care) was one of several pharmacies asked by the OIG to provide information as part of the investigation. *See* Ex. 34; Ex. 35, at 31:5-32:1; 103:22-106:4. Moreover, as set forth below, it was the OIG's investigations, and not any specialized knowledge or independent efforts of Ven-A-Care, that formed the basis for Ven-A-Care's claims against Dey.

E. The Cases Ven-A-Care Relies On Are Inapposite

Ven-A-Care's attempt to analogize the disclosures in this case to the disclosures in *United States ex rel. Cericola v. Federal National Mortgage Corp.*, No. CV 03-2294 GAF (VBKx), 2007 U.S. Dist. LEXIS 95783 (C.D. Ca. Nov. 27, 2007) and *Little v. Eni Petroleum Co., Inc.*, No. CIV-06-120-M, 2009 U.S. Dist. LEXIS 64697 (W.D. Okla. July 23, 2009) fails because, in those actions, the transactions giving rise to the FCA claims were substantially different from the transactions described in the public disclosures cited by the defendants. For instance, in *Cericola*, the court held that public disclosures of abusive practices by loan originators and contractors in inducing low and middle income borrowers to take out loans under the federal program did not bar *qui tam* claims against Fannie Mae for improperly certifying

certain home loans were made as part of that same federal program – when in fact they were not – on applications to HUD for default insurance on those loans. 2007 U.S. Dist. LEXIS 95783, *9-11, 24-31. Likewise, in *Little*, the court held that disclosures that natural gas producers failed to pay royalties to the federal government were not a bar to an FCA action against oil producers who improperly deducted transportation costs from their federal royalty payments. 2009 U.S. Dist. LEXIS 64697, *5-6. In contrast, the public disclosures cited by Dey all deal with the exact conduct and transactions that are at issue in Ven-A-Care's *qui tam* complaints, namely the claim that manufacturers reported AWPs and WACs that did not reflect Medicaid and Medicare providers' actual acquisition costs and resulted in payments by Medicaid and Medicare that substantially exceeded providers' actual acquisition costs, even to the point that the complaints allege the "spreads" already disclosed by the OIG Reports.

II. VEN-A-CARE IS NOT AN ORIGINAL SOURCE AS TO DEY

A. Ven-A-Care Had No Knowledge of Dey Independent of The OIG's Investigation

Ven-A-Care cannot avail itself of the "original source" escape hatch set forth in 31 U.S.C. § 3730(e)(4)(B) because it does not have any direct or independent knowledge of the claims against Dey. *See Ondis*, __ F.3d __, Slip. Op. at 18. There is no evidence in the record that Ven-A-Care ever dispensed or sought Medicaid or Medicare reimbursement for any of Dey's drugs prior to filing its first *qui tam* complaint against Dey. *See* Ex. 38, at 1080:14-1082:19. Indeed, Ven-A-Care had essentially stopped operating as a pharmacy by the mid-1990s. *See* Ex. 37, at 382:19-383:8; Ex. 38, at 1276:12-1277:6. The first time Ven-A-Care provided any information to the United States regarding Dey was in March 1996 along with pricing information for another manufacturer's albuterol, at the request of Robert Vito of the OIG, who at the time was in the midst of conducting a study of differences between Medicare

reimbursements and providers' actual costs for albuterol.[5] *See* Ex. 46, at 860:14-863:1; SJ Ex. 68 Ex. 43, at 267:9-272:18. Moreover, the so-called "insider information" Ven-A-Care contends establishes it as an original source consists solely of sales circulars, price lists, and prices that Ven-A-Care acquired second-hand from GPOs and wholesalers *See* Ex. 46, at 786:11-788:13; *see also* Ex. 46, at 815:8-816-6, 873:19-874:4, 883:20-890:6, 893:11-895:12; SJ Exhs. 70-72. As the First Circuit in *Ondis* recognized, "Congress plainly intended the FCA to encourage lawsuits by relators who have firsthand knowledge of fraud against the government." __ F.3d __, Slip. Op. at 13 (emphasis in the original). Accordingly, Ven-A-Care cannot qualify as an original source.

B. Ven-A-Care's Original Source Arguments Are Unavailing

Ven-A-Care attempts to divert the Court's attention away from the absence of "original source" evidence as to Dey by grouping its arguments regarding Dey with arguments concerning Roxane and Abbott and by citing to its knowledge of other alleged fraudulent schemes that are completely irrelevant to this action. However, as the Ninth Circuit held in *Seal 1 v. Seal A*, the fact that a relator has direct and independent knowledge concerning conduct by one entity does not make it an "original source" as to other entities alleged to have engaged in the same conduct, even if its disclosures to the Government concerning the first entity lead to the Government's discovery of the second entity. 255 F.3d 1154, 1163. Here, while Ven-A-Care may have provided the United States with information concerning some defendants and some allegedly fraudulent schemes, Ven-A-Care did not provide any information to the United States

[5] Ven-A-Care alleges that it first provided information regarding Dey to Government in August of 1995 and points to a single-page sales circular from a company called Pulmodose that it faxed to Mark Lavine at the United States Department of Justice on August 25, 1995. *See* Ex. 42. As set forth in Dey's opening brief, Ven-A-Care's own witness could not confirm that the sales circular contained pricing information for Dey's drugs. *See* Opening Brief at 17. Moreover, contrary to Ven-A-Care's allegations, there is no evidence that this constitutes an invitation to enter into "business arrangement" that would allow Ven-A-Care to receive "inflated spreads" for Dey's products, much less one organized by Dey.

concerning Dey until it forwarded a packet of material that included pricing information for Dey's drugs to Robert Vito in March 1996, in response to Mr. Vito's request for information regarding albuterol pricing. By that time, Mr. Vito's investigation into Albuterol UD pricing was well under way and he already had in his possession invoice pricing for Dey's drugs. That Ven-A-Care continued to forward second-hand pricing information for Dey's drugs to the United States after Mr. Vito's initial request cannot change the fact that it was Mr. Vito's investigation, and not any direct and independent knowledge possessed by Ven-A-Care, that formed the basis for Ven-A-Care's claims against Dey.

Nor do Ven-A-Care's contentions about its general status as a pharmacy "industry insider" and its general knowledge of pricing for pharmaceuticals save its claims. "If a relator merely uses his or her unique expertise or training to conclude that the material elements already in the public domain constitute a false claim, then a *qui tam* action cannot proceed." *Ondis,* __ F.3d __, Slip. Op. at 13. Moreover, at a recent deposition, a Ven-A-Care Rule 30(b)(6) witness testified that pharmacy industry insiders included manufacturers, wholesalers, group purchasing organizations, pharmacies, physicians, any legal purchaser of pharmaceuticals, and any other person involved in dispensing pharmaceuticals legally. *See* Ex. 48 at 430:21-434:13. Allowing anyone from this group, which likely numbers in the tens if not hundreds of thousands, to compare a wholesaler's price to a published AWP or WAC and then claim to be an "original source" is not the law: "Expertise that enables a relator to understand the significance of publicly disclosed information, without more, is insufficient to qualify him as an original source." *Ondis,* __ F.3d __, Slip. Op. at 21 (citations omitted).

Finally, since there is no evidence that Ven-A-Care ever purchased or dispensed any of Dey's drugs before commencing this action, Ven-A-Care cannot show that it has any "direct and

independent" knowledge concerning Dey. The two isolated, direct communications Ven-A-Care had with Dey are not sufficient to establish Ven-A-Care's "original source" status. *See* Declaration of Susan Schneider Thomas Submitting Exhibits Relied Upon In Ven-A-Care of the Florida Keys, Inc.'s Combined Opposition to Motions to Dismiss Filed by Abbott, Dey and Roxane ("Thomas Decl."), at Exs. BB and CC. The first communication is a January 15, 1996 letter from a Dey sales representative, Mari Carrell, to Luis Cobo, thanking Mr. Cobo for taking the time to discuss Dey Laboratories. *See* Thomas Decl. Ex. BB. There is no information in the letter concerning Dey's pricing or marketing practices or anything else that would support the allegations Ven-A-Care asserts against Dey. The second is a fax, dated August 22, 1996, from Ms. Carrell to Mr. Cobo, that includes a list of contract prices for Dey's drugs, as well as AWPs for two of Dey's albuterol products. *See* Thomas Decl. Ex. CC. This fax establishes nothing, as it was sent after the publication of the Pharmacy and Suppliers Reports. There is no evidence that Dey attempted to induce Ven-A-Care to dispense its albuterol products, as Ven-A-Care alleges, by the use of this fax. When examined on the document at a deposition, Mr. Cobo himself did not recognize the document at all. *See* Ex. 49 at 205:25-207:1. Ven-A-Care's 30(b)(6) designee could only confirm that it was Ms. Carrell who initially contacted Ven-A-Care, but could not testify whether Mr. Cobo requested the information or Ms. Carrell provided it on her own initiative. *See* Ex. 50 at 1098:22-1100:22. Finally, there is no evidence in the record that Ven-A-Care actually provided these documents to the United States prior to adding Dey to its *qui tam* complaints. Accordingly, they cannot be considered in determining Ven-A-Care's status as an original source. *See Natural Gas*, 562 F.3d at 1044 (holding that the only evidence to be considered on the question of a relator's status as an original source "is limited to information he voluntarily provided to the government before filing suit.")

III. THE UNITED STATES' COMPLAINT DOES NOT RELATE BACK TO RELATOR'S JURISDICTIONALLY DEFECTIVE COMPLAINT UNDER FEDERAL RULE OF CIVIL PROCEDURE 15(C)

Since the Court lacks jurisdiction over Ven-A-Care and its *qui tam* complaints, the United States' complaint in intervention cannot relate back to these complaints. An amended complaint cannot relate back to an original complaint that has been dismissed for lack of subject matter jurisdiction. "[I]t is axiomatic that in order for the doctrine of relation back to apply, the prior pleadings must be properly filed and the court must have jurisdiction over the claim at the time of the prior pleadings." *Austin v. Trandell*, 207 F.Supp.2d 616, 624-26 (E.D. Mich. 2002); *see also* Fed. R. Civ. P. 15(c). For instance, in *White v. Louisiana*, the Fifth Circuit held that a claim that was barred by the statute of limitations could not be revived under Federal Rule of Civil Procedure 15 (c) by relating back to a jurisdictionally defective complaint. 178 F.3d 1291 (5th Cir. 1999); *see also Kreider Dairy Farms, Inc. v. Glickman*, 190 F.3d 113, 121 (3d Cir. 1999). Relation back is prohibited here, too, because there was never subject matter jurisdiction over the original *qui tam* complaint against Dey. Indeed, this Court has already held that "if the Court did not have jurisdiction over Ven-A-Care's first pleading, the government's complaint-in-intervention cannot properly relate back." *In re Pharm. Indus. Average Wholesale Price Litig. (U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc.)*, 498 F.Supp.2d 389, 399-400 (D. Mass. 2007).

The United States points to no authority to support departure from this basic procedural principle or this Court's prior holding. Instead, the United States resorts to citing to authority that is silent on this issue, namely the Supreme Court's decision in *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007), and the recent amendments to the FCA.

The Supreme Court in *Rockwell* only addressed the issue of original source under the FCA, and found that the relator was not an original source because he did not have direct and

independent knowledge. *Rockwell*, 549 U.S. at 460-79. It then directed the Tenth Circuit to eliminate the relator from the action and the prior judgment. *Id*. at 478-79. Following remand from the Supreme Court, the Tenth Circuit simply affirmed the decision of the Supreme Court and further remanded the case to the District Court of Colorado. *United States ex rel. Stone v. Rockwell Int'l Corp.*, 492 F.3d 1157 (2007). Neither the Supreme Court nor the Tenth Circuit even considered, much less resolved, how the relator's dismissal would affect the applicability of the statute of limitations to the Government's claims. The Supreme Court's silence on this issue cannot be read as having affirmatively carved out an exception to the normal operation of Rule 15(c) and subject matter jurisdiction for FCA *qui tam* complaints.[6]

The United States' arguments concerning the new relation back provisions in the FCA fare no better. The United States asks the Court to presume that, because Congress did not explicitly state that a complaint-in-intervention could not relate back to a jurisdictionally defective *qui tam* complaint, Congress must have intended *sub silentio* to allow relation back even if the court had no subject matter jurisdiction at the time. This argument is wrong. The language of the relation back provision in the new 31 U.S.C. §3731(c) is almost identical to that of Rule 15(c), and only states that any government pleading shall relate back to the original relator's complaint for statute of limitations purposes. It is axiomatic that the initial complaint must confer subject matter jurisdiction before relation back can occurr. Federal courts are courts of limited jurisdiction and subject matter jurisdiction must be explicitly conferred by statute or by the Constitution. *See Kokkonen v. Guardian Life Ins. Co. of America*, 511 U.S. 375, 376; *see also Mineral Resources Intl. v. United States Dept. of Health and Human Serv.*, 53 F.3d 305, 308 (10th Cir. 1995) (dismissing claims in the absence of an express Congressional grant of subject

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6 *Connectu LLC v. Zuckerberg*, 522 F.3d 82 (1st Cir. 2008), is not controlling either. The case was not an FCA case and did not turn on the question of relation back to a jurisdictionally-defective complaint at all.

matter jurisdiction because "we are reluctant to infer new legislative provisions out of Congressional silence"). The United States's argument that its complaint can relate back to a jurisdictionally-defective Relator's complaint must fail since the Court had no subject matter jurisdiction at that time.

CONCLUSION

For the foregoing reasons, and the reasons set forth in Dey's Memorandum of Law in Support of its Motion to Dismiss Relator's Complaints for Lack of Subject Matter Jurisdiction, Dey respectfully requests that the Court dismiss Ven-A-Care's complaints, with prejudice, as to Dey, and grant Dey such other, further, and different relief as the Court deems to be just and proper.

Dated: November 23, 2009

Respectfully Submitted,

/s/ Sarah L. Reid
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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on November 23, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/Sarah L. Reid
Sarah L. Reid